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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/659,951

09/10/2003

Todd Allen Berg

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ROPES & GRAY LLP  
PATENT DOCKETING 39/361  
1211 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036-8704

EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |                                    |  |
|------------------------------|---|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/659,951      | <b>Applicant(s)</b><br>BERG ET AL. |  |
|                              | <b>Examiner</b><br>JENNIFER L. HORNBERGER | <b>Art Unit</b><br>3734            |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Terminal Disclaimer***

1. The terminal disclaimer filed on 02/20/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,416,527 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. (US 6,190,353) in view of Kornberg et al. (US 5,353,804).

Regarding claims 1-6 and 8-11, Makower et al. disclose an apparatus for cutting an aperture in a side wall of a patient's blood vessel comprising: a curvable delivery sheath (100, 700), the delivery sheath configured to move axially along the interior of the blood vessel such that the distal end is proximate to an access site on the side wall; a curvable tissue piercing structure (GW; Fig. 7d) having a longitudinal axis and being configured to pierce the side wall passing axially along the interior of the sheath through the side wall substantially parallel to the longitudinal axis, wherein the tissue-piercing structure is capable of deflecting transversely after passing through the side wall and independently passes through all of the tissue to be pierced without any external means of support; and a hollow curvable annular tissue-cutting catheter (102; Fig. 7d) disposed annularly around the tissue-piercing structure and configured for movement substantially

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parallel to the longitudinal axis for rotation about the longitudinal axis to produce an annular cut through the side wall and to thereby sever from the side wall a disc of tissue that was previously pierced by the tissue-piercing structure, the tissue-cutting catheter, having a circular tissue cutting edge and capable of receiving the disc in its hollow, being mounted for movement relative to the tissue-piercing structure substantially parallel to the longitudinal axis and capable of cutting through the side wall in the same direction as the tissue piercing structure (Fig. 12).

Makower et al. fail to disclose a plurality of resilient structures mounting on the tissue piercing structure. Kornberg et al. disclose a guidewire having a plurality of resilient structures, mounted in an annular array around the longitudinal axis, for anchoring the guidewire in place with respect to the area to be cut (col. 7, ln. 44-49 and ln.52-55; Figures 6 and 8). Each of the resilient structures has a distal portion and proximal portion, the distal portion being closer to the end of the tissue piercing structure that is first to pass through the side wall, the resilient structure being secured to the tissue-piercing structure adjacent the distal portion, and the proximal portion being resiliently biased to spring radially outwardly from the tissue piercing structure. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the guidewire of Makower et al. to include a plurality of resilient structures in order to anchor the guidewire with respect to the vessel wall.

3. Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. and Kornberg et al. as applied to claim 1 above, and further in view of van der Gaast (US 3,577,979).

Makower et al. as modified by Kornberger et al. fail to disclose the tissue-cutting catheter has a serrated tissue cutting edge. However, van der Gaast teaches that a circular cutting edge of a surgical punch should be serrated in order to obtain the

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advantage of reducing tearing of the tissue (col. 2, ln. 35-39). It would have been obvious to one of ordinary skill in the art to make the cutting edge of Makower et al. serrated to allow for a cleaner cut through the vessel wall.

### ***Response to Arguments***

4. Applicant's arguments, see page 4, filed 02/20/08, with respect to the rejection(s) of claim(s) 1-11 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Makower et al. and Kornberger et al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JLH

08/28/08

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731